In re Application of: Doron LANCET et al
Serial No.: 10/511,278
Filed: October 22, 2004
Office Action Mailing Date: March 27, 2007

Examiner: Carla J. Myers
Group Art Unit: 1634
Attorney Docket: 28364

REMARKS

Claims 1-33 are pending.

Claims 1-22, 27 and 30-33 are withdrawn.

Claims 23-26, 28 and 29 are currently under examination.

Claims 23 and 28 are currently amended.

Claims 25, 26 and 29 are cancelled herewith.

New claim 34 is entered herewith.

The specification is objected to.

The drawings are objected to.

Claim 29 is objected to.

Claims 23-26, 28 and 29 are rejected under 35 USC § 101 as lacking utility.

Claims 23-26, 28 and 29 are rejected under 35 USC § 112, first paragraph, as lacking enablement.

Claims 23-26, 28 and 29 are rejected under 35 USC § 112, first paragraph, as lacking sufficient written description.

Claims 23-25 and 28 are rejected under 35 USC § 102(b).

Claims 26 and 29 are rejected under 35 USC § 103(a).

Objections to the specification

The specification is objected to for containing embedded hypertext links. The Examiner cites MPEP §608.01 which prohibits the use of browser executable code in the specification. The Applicants identified and corrected URLs presented as hypertext links in the following places in the specification: page 7 (lines 10-16); Page 11 (lines 16-21); Page 12 (lines 3 to 8); Page 14 (lines 1-2) and Page 50 (lines 23 to 33).

In each instance the correction is in the form of http://name.domain.country to -- http://nameDOTdomainDOTcountry --. The Applicants respectfully suggests that while this correction satisfies the requirements of MPEP §608.01, the correction: (1) does not introduce new matter into the specification and (2) does not reduce the amount of information available to a human reader.

With regard to the link on page 50 of the specification, the Applicants have communicated with the webmaster of the internet site (see Appendix B) and provided a complete URL. The webmaster indicated that an automatic redirect from the URL as originally published in the specification seems to be malfunctioning. The complete URL as entered hereinabove by amendment provides access to the WWW page which would have been available using the URL as it originally appeared in the specification. The Applicants respectfully suggest that correction of the URL does not introduce new matter into the specification.

Objections to the drawings

The drawings are objected to because they comprise color illustrations. The Applicants file herewith a petition under 37 CFR 1.84(a)(2) and a fee as set forth in 37 CFR 1.17(h).

The Applicants respectfully suggest that this petition and fee address the Examiner's objection.

Objections to the claims

Claim 29 is objected to under 37 CFR 1.75 as being a duplicate of claim 26.

The Applicants responds by cancelling claim 29. The Applicants respectfully suggests that cancellation of claim 29 addresses the Examiner's objection.

35 USC § 101 rejection: utility

Claims 23-26, 28 and 29 are rejected under 35 USC § 101 as lacking utility. The Examiner has devoted numerous pages of the office action to the issue of "credible, substantial, specific or well established utility."

Specifically, the Examiner states:

(page 6 of the current office action) "*The specification fails to provide objective evidence of a specific activity for the claimed olfactory receptor nucleic acids containing allelic variants polymorphisms and thereby a utility for the methods of detecting allelic variants.*";

(page 7 of the current office action) *"The specification does not teach a particular biological activity associated with the OR11H7P pseudogene or any of the additional genes and allelic variants thereof set forth in the present specification";*

(page 7 of the current office action) *"However, the specification does not teach a clear nexus between any particular OR polymorphisms and the phenotype of smell perception"*

(page 7 of the current office action) *"To establish a specific and substantial activity for the OR allelic variants would require a showing that the presence of the OR allelic variant is associated with a particular type of smell perception."*

(page 8 of the current office action) *"...the specification does not clearly teach how one can use the information obtained from typing."*

(page 8 of the current office action) *"Support for an asserted utility that is specific and substantial would require, for example, a showing of a particular function for the OR allelic variants, or a showing of a clear correlation between the disclosed OR allelic variants and the occurrence of a particular condition."*

The Applicants respectfully traverse the Examiner's rejection under §101.

As set forth in the inventor's declaration, one of ordinary skill in the art of Olfactory Receptor Research would intuitively understand the credible utility of ***typing the subject with regard to the subject's olfactory perception*** as instantly claimed. Examples of cases where it can be advantageous to screen individuals for olfactory perception include, but are not limited to *a priori* screening for employment positions in olfaction related professions (e.g. sommelier, whiskey blender, perfume formulary).

The Applicants hereby submit a declaration by the inventor accompanied by new experimental data (Appendix A) which was obtained following filing of the instant application while using its teachings. The declaration attests to the authenticity of the results, and to the fact that they were achieved using methods described in the disclosure and that the results provide the requisite degree of enablement and/or utility for what is claimed.

The Applicants respectfully call the attention of the Examiner to Page 20, lines 7 to 29 (***emphases*** added) of the specification:

In re Application of: Doron LANCET et al
Serial No.: 10/511,278
Filed: October 22, 2004
Office Action Mailing Date: March 27, 2007

Examiner: Carla J. Myers
Group Art Unit: 1634
Attorney Docket: 28364

The generation of such distinct genetic populations provides evidence that ***a strong relationship exists between sequence variability in ORs and odorant-specific olfactory threshold variability.***

Thus, the present finding serve as the basis for ***correlating between the genotype and phenotype of olfactory perception.*** *For example, if an allelic variant (pseudogene) is a low frequency allele in a specific individual, it would likely correlate to a specific anosmia, since it is a low frequency functional disruption. Contrarily,* ***a high frequency OR allele present in a specific population or subpopulation could indicate a specific hyperosmia, a high odorant sensitivity present in that particular population or subpopulation.*** *Utilizing these and other guiding principles, the present OR typing approach can be utilized to* ***elucidate the linkage between an individuals genotype and olfactory perception.***

Elucidation of such a genotypic-phenotypic relationship can be effected by testing human volunteers from diverse ethnic groups which show clear genotypic variations in at least one, preferably several or more preferably all of the OR SPGs (allelic variants) described herein for threshold sensitivity to several odorants. *The threshold sensitivities towards each odorant are expected to form a distribution in which its two ends will be determined as "hyposmic" (low sensitivity) and "hyperosmic" (high sensitivity). In addition, the functionality of the different OR SPGs will be determined in each individual by SNP genotyping in a high-throughput manner. Statistical analysis will then be used to identify significant correlation between specific odorant sensitivity and a particular OR allele, which might also indicate a specific interaction between the two molecules.*

The Applicants respectfully suggest that this portion of the specification makes it clear that experimental results presented in Appendix A are described as part of the invention in the specification as originally filed. Appendix A establishes that isovaleric acid is the odorant of the OR11H7P olfactory receptor and that analysis of a C to T point mutation at position 679 of the coding sequence of the receptor can be

In re Application of: Doron LANCET et al
Serial No.: 10/511,278
Filed: October 22, 2004
Office Action Mailing Date: March 27, 2007

Examiner: Carla J. Myers
Group Art Unit: 1634
Attorney Docket: 28364

used to predict olfactory sensitivity to this odorant. The Applicants note that reference to position 691 in the Office Action refers to a number of bases from the beginning of SEQ ID No.: 81, and not to a number of bases from the initiator ATG codon, as clearly claimed.

Experimental data presented in Appendix A merely confirms what was stated in the cited portion of the specification, namely that there is a correlation ***between the genotype and phenotype of olfactory perception.***

In order to explicitly claim what was already inherent in independent claim 23, the claim has been amended to read:

A method of typing a subject according to presence or absence of allelic variants of an olfactory receptor gene, the method comprising detecting the presence or absence of the allelic variant of an olfactory receptor gene of OR11H7P as set forth in SEQ ID NO: 81 in a biological sample of the subject using an oligonucleotide as set forth in SEQ ID NO: 29, thereby typing the subject ***with regard to the subject's olfactory perception.***

Support for the added limitation is found in the portion of the specification cited above so that no new matter is introduced by the amendment.

Applicants now traverse the Examiner's rejections of the claims based upon claim 23 as currently amended. Appendix A, which is currently of record, establishes, in the Examiner's own words, " ***a specific activity for the claimed olfactory receptor nucleic acids containing allelic variants polymorphisms"*** and/or " ***a particular biological activity associated with the OR11H7P pseudogene"*** and/or " ***a clear nexus between any***[a] ***particular OR polymorphisms and the phenotype of smell perception"***and/or that ***"the presence of the OR allelic variant is associated with a particular type of smell perception"*** and/or ***"a clear correlation between the disclosed OR allelic variants and the occurrence of a particular condition."***

Additionally, the Applicants respectfully suggest that Appendix A, in conjunction with page 20, lines 7 to 29 (set forth hereinabove) make it abundantly clear ***"how one can use the information obtained from typing."*** Amendment to claim 23 introduces a specific and credible utility into the body of the claim itself by specifying "...thereby typing the subject with regard to the subject's olfactory

perception." Support for this amendment is present in the specification as originally filed as explained hereinabove.

In view of the above remarks and claim amendments, the Applicants respectfully request that the Examiner withdraw the §101 rejection of claims 23-26 and 28.

35 USC § 112 rejection: enablement

Claims 23-26, 28 and 29 are rejected under 35 USC § 112, first paragraph, as lacking enablement citing the Wands factors. The Applicants respectfully traverses the Examiner's §112 rejection.

Specifically, the Examiner suggests (**emphases** added) that since "the claimed invention is not supported by **either a specific and substantial asserted utility or a well established utility** for the reasons set forth above, **one skilled in the art would not know how to use the invention.**"

The Applicants respectfully suggest that the §112 enablement rejection is moot in view of the **specific and substantial asserted utility** as set forth in detail hereinabove. In view of this utility, there can be no question that one of ordinary skill in the art would **know how to use the invention.**

The Applicants respectfully suggest that independent claim 23 as currently before the Examiner meets the enablement requirements of §112, first paragraph.
In view of the above arguments it is submitted that the present invention as claimed is fully enabled. Withdrawal of the Examiner's rejection based upon the enablement requirements of §112, first paragraph is respectfully requested.

35 USC § 112 rejection: written description

Claims 23-26, 28 and 29 are rejected under 35 USC § 112, first paragraph, as lacking sufficient written description.

Specifically, the Examiner states that the claims "... contain subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors(s) at the time the application was filed, had possession of the claimed invention."

In re Application of: Doron LANCET et al
Serial No.: 10/511,278
Filed: October 22, 2004
Office Action Mailing Date: March 27, 2007

Examiner: Carla J. Myers
Group Art Unit: 1634
Attorney Docket: 28364

The Applicants respectfully traverse the Examiner's rejection based upon §112 written description requirements. The Applicants point out that the scope of claim 23 following the previous restriction requirement in this case is narrow. Specifically, claim 23 is directed towards identifying a specific mutation in OR11H7P (SEQ ID NO: 81) at position 679 of the coding sequence of the receptor using a specific oligonucleotide (SEQ ID NO:29).

The Applicants respectfully refer again to the specification at page 20, lines 7 to 29, as cited above and points out to the Examiner that olfactory threshold measurement techniques were published and well known to those of ordinary skill in the art well before the priority date of the instant application (e.g. Hummel et al. (1997) Chem Senses *22*, 39-52).

In summary, the current independent claim is directed towards ascertaining whether there is a C or a T at a specific position in an OR sequence. At the time the application was filed, the well known and available olfactory threshold measurement techniques made determination of the phenotype associated with the point mutation a matter of routine calibration.

The Applicants respectfully suggest that independent claim 23 as currently before the Examiner meets the written description requirements of §112, first paragraph. Withdrawal of the Examiner's rejection based upon the written description requirements of §112, first paragraph is respectfully requested.

35 USC § 102(b) rejections

Claims 23-24 and 28 are rejected under 35 USC § 102(b). Specifically, claims 23, 24 and 28 are rejected as being anticipated by Sharon et al. (Gene (2000) 260:87-94; hereinafter Sharon) and claims 23-25 and 28 are rejected as being anticipated by WO 2001/27158 pages 1-53, 73, 226 and 145 to 149; hereinafter Bellenson). The Applicants respectfully traverse the Examiner's §102 rejections.

Claim 23 as currently before the Examiner is directed towards (***emphases*** added):

> *A method of* ***typing a subject*** *according to presence or absence of allelic variants of an olfactory receptor gene, the method comprising detecting the* ***presence or absence of the allelic variant of an olfactory receptor gene of***

OR11H7P as set forth in SEQ ID NO: 81** in a biological sample of the subject **using an oligonucleotide as set forth in SEQ ID NO: 29, thereby typing the subject with regard to the subject's olfactory perception.

With respect to the §102(b) rejection based upon Sharon, the Applicants respectfully suggest that Sharon does not teach, hint or fairly suggest ***typing a subject*** based upon ***presence or absence of the allelic variant of an olfactory receptor gene of OR11H7P as set forth in SEQ ID NO: 81*** and also does not teach ***using an oligonucleotide as set forth in SEQ ID NO: 29,***as instantly claimed

The Applicants remind the Examiner that the previous election in this case limits the claim scope to receptor OR11H7P (SEQ ID No.: 81) and analytic oligonucleotides which detect a C to T mutation at position 679 from the initiation codon (SEQ ID No.: 29). Sharon describes only different allelic variation in the receptor OR17 and does not even hint or suggest that OR11H7P exists, let alone that it could be useful in ***typing the subject with regard to the subject's olfactory perception*** as instantly claimed.

The Applicants respectfully suggest that the Examiner has made no *prima facie* case for a §102 rejection based upon Sharon because Sharon does not each any allelic variants in OR11H7P.

With respect to the §102(b) rejection based upon Bellenson, the Applicants respectfully submit that although Bellenson describes a "T" at position 679 of Bellenson SEQ ID No.: 555, there is no hint or suggestion in Bellenson that the residue in question could ever be a "C".

Because Bellenson does not teach that "T" at position 679 is an allelic variant, Bellenson cannot be said to teach ***typing a subject*** based upon ***presence or absence of the allelic variant of an olfactory receptor gene of OR11H7P as set forth in SEQ ID NO: 81*** as instantly claimed.

The Applicants respectfully suggest that the Examiner has made no *prima facie* case for a §102 rejection based upon Bellenson because Bellenson does not each any allelic variants at position 679 in OR11H7P.

In summary, the Applicants respectfully suggest that there is no *prima facie* case for a §102 rejection currently of record in this case because the cited art does not teach all of the claimed limitations.

35 USC § 103(a) rejections

Claims 26 and 29 are rejected under 35 USC § 103(a) as being unpatentable over Bellenson in view of NCBI SNP Database (RS 1953558, January 3, 2001; hereinafter NCBI).

Claim 29 has been cancelled. With regard to claim 26, it depends from claim 23 (emphases added):

> *A method of typing a subject according to presence or absence of allelic variants of an olfactory receptor gene, the method comprising detecting the presence or absence of the allelic variant of an olfactory receptor gene of OR11H7P as set forth in SEQ ID NO: 81 in a biological sample of the subject using an oligonucleotide as set forth in SEQ ID NO: 29, thereby* ***typing the subject with regard to the subject's olfactory perception.***

The Applicants respectfully suggest that neither Bellenson nor NCBI teaches or suggests ***typing the subject with regard to the subject's olfactory perception*** nucleotide at position 679 of SEQ ID No.: 81 (with respect to the initiation codon) as instantly claimed.

Thus, even if one of ordinary skill in the art were to combine Bellenson with NCBI, such combination would not produce all of the claimed limitations.

The Applicants respectfully suggest the claim 26 as currently before the Examiner is patentable over Bellenson in view of NCBI at least by virtue of its dependence from claim 23.

New Claim

New claim 34 is entered herewith. The Applicants respectfully suggest that new claim 34 reads on the elected invention. The new claim is enabled, has utility and is free of the cited art at least for the reasons set forth hereinabove for independent claim 23.

In re Application of: Doron LANCET et al
Serial No.: 10/511,278
Filed: October 22, 2004
Office Action Mailing Date: March 27, 2007

Examiner: Carla J. Myers
Group Art Unit: 1634
Attorney Docket: 28364

All issues raised by the Examiner have been addressed. Prompt notice of allowance is respectfully and earnestly requested.

Respectfully submitted,

Martin D. Moynihan
Registration No. 40,338

Date: July 26, 2007

Encl.:

Appendix A

Appendix B

Executed Declaration of Prof. Doron Lancet under 37 CFR 1.132

Curriculum vitae of Prof. Doron Lancet

Petition for Extension (one month)

Petition for Color Drawings/3 sets of color figures

Additional Claim Transmittal Sheet